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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,165	02/22/2002	Andreas Lubbertus Aloysius Johannes Dekker	41942-04510	8432
25231	7590	01/16/2004	EXAMINER	
MARSH, FISCHMANN & BREYFOGLE LLP			MALLARI, PATRICIA C	
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SUITE 411			ART UNIT	PAPER NUMBER
AURORA, CO 80014			3736	
DATE MAILED: 01/16/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/081,165	DEKKER, ANDREAS LUBBERTUS ALOYSIUS JOHA	
	<b>Examiner</b>	<b>Art Unit</b>	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 October 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2,4-15,17-29 and 31-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 14,15 and 17-24 is/are allowed.
- 6) Claim(s) 1,2,4-9,25-29,31,32,37-39 and 43-45 is/are rejected.
- 7) Claim(s) 10-13,33-36,40-42 and 46 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 19 May 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

***Drawings***

The drawings were received on 5/19/03. These drawings are approved.

***Claim Objections***

Claim 6 is objected to because of the following informalities: on lines 2-3 of the claim "step of using" should be replaced with "step of monitoring". Appropriate correction is required.

Claims 44 and 45 are objected to because of the following informalities: on line 2 of each claim, "comprises by acquiring" should be replaced with "comprises acquiring". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites the limitation "the first and second". There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 4-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Turcott. Turcott discloses a method wherein heart rate variability (HRV) analysis includes distinguishing the effects of a respiratory component in the frequency range of 0.17 Hz to 0.4 Hz and a Mayer wave component in the frequency range of 0.03 Hz to 0.1 Hz, where both the Mayer wave and respiratory components are information related to both blood pressure and heart rate. Turcott further teaches that HRV analysis can be applied using pulse times determined from a vascular plethysmography signal (blood volume) using a reflectance optical system having a light source 26 having parallel red and infrared LEDs, a light detector 28, and associated circuitry, where the pleth signal is narrow-band filtered before further processing. The distinguished fluctuations in the respiratory component and the Mayer wave component are used to monitor disease status (figs. 1, 2, 5, 5a, 8, 11, 13).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-9, 25-29, 31, 32, 37-39, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saitoh et al. in view of Turcott. Saitoh discloses obtaining and processing an RR signal, which is a measure of heart rate variability

(HRV), and using a digital signal processor 10 to distinguish a first component, a Mayer Wave related sinus Arrhythmia signal (MWSA) indicating heartbeat interval fluctuations regarding a respiratory motion, and a second component, a respiratory sinus arrhythmia value (RSA) indicating a fluctuation of heartbeat intervals regarding a blood pressure fluctuation. The CPU 11 uses a ratio, indicating a difference between the two values, of the MWSA and RSA values, multiplied by a judgment coefficient n4 in (see steps S107, S123 and S132) to monitor the sleepiness, fatigue, and/or impatience of the person being monitored (figs. 1, 4, 5a-e, 6, 9, 10, 12-14). Saitoh teaches obtaining the RR signal by using a minor tremor pickup/ skin vibration sensor, rather than a photoplethysmograph.

However, Turcott teaches that a variety of measuring means, including vascular plethysmography and mechanical transduction, may be utilized to obtain HRV information, as long as contraction times of the heart may be identified. A vascular plethysmography signal may be obtained using a reflectance optical system having a light source 26 having parallel red and infrared LEDs, a light detector 28, and associated circuitry (figs. 1, 2, 5, 5a, 8, 11, 13; col. 16, lines 11-55; col. 18, line 41-col. 19, line 25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a photoplethysmograph in place of the skin vibration sensor in the invention of Saitoh, since Turcott teaches the two sensors as being functionally equivalent in HRV analysis.

***Response to Arguments***

Applicant's arguments with respect to claims 1-9, 13-20, 24-32, and 36 have been considered but are moot in view of the new ground(s) of rejection.

***Allowable Subject Matter***

Claims 10-13, 33-36, 40-42, and 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 14, 15, and 17-24 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding the allowability of claims 10-12, 33-35, and 40-42, the prior art fails to teach or suggest using said first information and second information to obtain a third information related to a phase or a waveform difference between the first and second signals.

Regarding the allowability of claim 13, the prior art fails to teach or suggest using at least one distinguished effect, where the effect is related to a respiratory component or a Mayer wave component, to measure the patient's respiration rate.

Regarding the allowability of claim 36, the prior art fails to teach or suggest the combination of measuring a patient's respiration rate with the claimed distinguishing the effects associated with either the first or second component by determining a third information related to a difference between the first and second signals.

Regarding the allowability of claim 46, the prior art fails to teach or suggest using said distinguished effect, associated with either a first component associated with the

operation of the respiratory system or a second component associated with the autonomic nervous system to monitor respiration rate.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

The following is an examiner's statement of reasons for allowance, with regard to claims 14, 15, and 17-24: The prior art of record fails to teach or fairly suggest a method comprising the steps of isolating a pulsatile pleth signal and a baseline pleth signal from a pleth signal, and then processing the baseline pleth signal to distinguish effects associated with a first respiratory component from the effects associated with a second Mayer wave component. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Mon-Fri 9:30 am-7:00 pm (alternate Fri. off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 746-8117.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

*Patricia Mallari*  
pcm

*Robert & Weiss L*  
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JULY 1 2003